

No. 13062

United States
Court of Appeals
For the Ninth Circuit.

ALBERTY FOOD PRODUCTS, a Partnership,
and ADA J. ALBERTY, HARRY AL-
BERTY, FLORENCE ALBERTY, MAR-
GARET QUINN and HELEN HACK-
WORTH, Individually and as Copartners,
Appellants,

vs.

UNITED STATES OF AMERICA,
Appellee.

Transcript of Record

Appeal from the United States District Court,
Southern District of California,
Central Division.

FILED

NOV 14 1951

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[Clerk's Note: When deemed likely to be of an important nature, errors or doubtful matters appearing in the original certified record are printed literally in *italic*; and, likewise, cancelled matter appearing in the original certified record is printed and cancelled herein accordingly. When possible, an omission from the text is indicated by printing in *italic* the two words between which the omission seems to occur.]

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In the United States District Court for the Southern
District of California, Central Division

Civil Action No. 10,322 W

UNITED STATES OF AMERICA,

Plaintiff,

vs.

ALBERTY FOOD PRODUCTS, a Partnership,
and ADA J. ALBERTY, HARRY ALBERTY,
FLORENCE ALBERTY, MARGARET
QUINN, and HELEN HACKWORTH, In-
dividually and as Co-partners,

Defendants.

AMENDED COMPLAINT FOR INJUNCTION

United States of America, plaintiff herein, by and through James M. Carter, United States Attorney for the Southern District of California, Central Division, respectfully represents to this Honorable Court as follows:

1. This proceeding is brought under section 302(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 332(a)], hereinafter referred to as "the Act," specifically investing the several United States District Courts with jurisdiction to enjoin and restrain violations of section 301 of said Act (21 U.S.C. 331) as hereinafter more fully appears.

2. The defendant, Alberty Food Products, is a partnership having its principal place of business at 729 N. Seward Street, Hollywood, California. The

partnership also trades and does business under the name of Cheno Products. The defendants, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, residents of the County of Los Angeles, State of California, are primarily responsible for the policies and activities of the partnership. [2*] Alberty Food Products and the defendants, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, are the manufacturers, packers, and distributors of certain articles of drug hereinafter designated by name.

3. Such drugs are designated by name, as follows: Alberty's Vegetable Compound Capsules; Alberty's Oxorin; Alberty's Food Regular; Instant Alberty Food; Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles); Alberty's Sabinol; Alberty Phloxo B Tablets; Alberty's Phosphate Pellets; Alberty's Riol Tablets; Alberty's Rico Tablets; Alberty Special Formula Tablets; Alberty's Vitamin A (High Potency) Shark Liver Oil; Alberty's Vi-C; Wheat Germ Oil; Alberty's Vitamin B Complex Tablets with High-Potency B1; Alberty's Vitamin B1 with Supplementary Amounts of Other B Complex Factors; Alberty's Lebara Pellets, Plain; Alberty's Lebara Pellets; No. 2; Cheno Herb Tea; Cheno Phytolacca Berry Juice Extract Tablets; Cheno Combination Tablets; Tablets Pandora; Recal Tablets; Alberty's Vio-Min Vitamin-Mineral Tablets; Alberty's R-Gon Tablets;

*Page numbering appearing at foot of page of original Certified Transcript of Record.

Alberty's Laxative Blend Tea; Alberty's Ca-Mo Pellets; Alberty's Vitamin A and G Perles; Alberty's Rego.

4. For some years, defendants have introduced said articles of food and drug into interstate commerce, and have caused said articles to be accompanied by various leaflets and booklets when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce. Said leaflets and booklets are entitled "Calcium, The Staff of Life," "Dynamic Digests," "Is There Hope That Graying Hair Can Be Restored? Read What Science Says—Pandora," "Health Mysteries?," "Happy Figures by the Cheno Plan," "Reduce! Streamline Your Figure—Follow the 5 Factor Cheno Plan." Each of these booklets and leaflets relates to one or more of the above-mentioned articles of drug and contains false and misleading statements (a) regarding the nutritional and health-giving qualities of said articles, (b) regarding the effect of said articles on the structure and functions of the human body, and (c) in that they represent and suggest that such articles are effective in the treatment, prevention, and cure of the diseases, symptoms, and conditions as hereinafter specified: [3]

(a) Alberty's Vegetable Compound Capsules:

Health Mysteries (page 16)

Malfunctions of certain organs rendering persons unable to tolerate starch and sugar in the

same proportions as the normal individual (diabetes).

Calcium, *The Staff of Life* (page 48)

For diabetes

(b) Alberty's Oxorin

Health Mysteries (pages 16 and 26)

Dynamic Digests (page 15)

Pernicious anemia; lack of strength and vitality; need of more sleep than is normally required; chronic fatigue; low blood pressure, poor circulation, and lowered resistance to infection; gas after eating; providing robust bouyant health and stamina; a condition in which one is weary, tired, rundown, just dragging oneself around with no ambition left, when every effort one makes seems to leave one weak and spent; weakness; thinness, and preventing the lowering of the natural resistance of the body while the starch and sugar intake is kept at a minimum in persons suffering from malfunction of certain organs rendering them unable to tolerate starch and sugar in the same proportions as the normal individual.

Calcium, *The Staff of Life* (pages 46-48)

For diabetes. For early fatigue, weakness, low blood pressure, pernicious anemia; to provide buoyant health, to benefit general lassitude, weary, general "rundown" feeling, lowering resistance.

(c) Alberty's Food Regular, and Instant Alberty Food

Health Mysteries

(pages 16, 20, 21, 22, 23, 26, 35)

Dynamic Digests

(pages 2, 3, 6, 16, 17, 19, 28)

Giving relief in a few days to persons suffering from ulcers, colitis, and hyperacidity; enabling thousands [4] to receive new strength and vitality within a short time; ulcerated stomach; relieving anemia and general rundown condition in persons suffering from malaria fever; curing in eight months duodenal ulcers of five years' standing; tuberculosis; relieving stomach trouble; remedying deficient conditions where certain cells, tissues and glands have been affected through the medium of the nervous system, blood, cells, tissues, liver, kidneys and other glands of the body; remedying urinary discomforts; remedying arthritis or rheumatism; building blood; furnishing mineral elements and nourishment so that the natural resistance of the body is not lowered and the starch and sugar intake is kept at a minimum in persons suffering from malfunction of certain organs rendering them unable to tolerate starch and sugar in the same proportions as the normal individual; (in addition further representations in the case of Instant Alberty Food) assuring strong, healthy bodies for the joyous years ahead; providing increased

strength, pep and stamina; remedying pale, weak, undernourished conditions; thin and scrawny bodies; preventing or remedying "falling below par"; and continued weakness and tiredness; remedying eczema;

Calcium, *The Staff of Life* (pages 6, 7, 8, 10 to 23 inclusive, 38, 48, 49, 50, 62 and 63, 65 and 66, and 44)

For diabetes. For nervousness, nausea, diarrhea, stomach irritation, malassimilation, pain on eating, underweight; for changing one's personality; making a positive personality out of a negative personality; effecting a more youthful appearance; to counteract stomach distress and yellowing of the skin, to remedy [5] severe pain and other symptoms of an upset digestive tract; for stomach and intestinal pain; mucous colitis, stomach distress, catarrhal condition; for enabling sickly, premature, and cadaverous infants to become well and healthy, infantile eczema, gastric ulcer, malassimilation, inability to gain weight, dormant liver, toxic condition, soft and flabby flesh; remedy prolapse of the intestines; overcome faulty nutrition and the effects of faulty nutrition, toxemia, liver, or urinary disorders and ailments that have been years in developing, gastric ulcer, arthritis, rheumatism, kidney involvement, general run-down condition, malnutrition, acidity, hay fever, eczema, vomiting, toxic poisons,

disturbed nervous system, kidneys unable to excrete poisons; for eliminating toxic poisons and fixed acids and causing liver, kidneys, and other vital organs to function normally; for deficiency conditions where cells, tissues and glands have been affected; as a remedy for hay fever, hives, and acne; for clearing the skin; for sinusitis, for scurvy, rickets and anemia.

(d) **Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles)**

Health Mysteries (pages 23 and 24)

Dynamic Digests (page 23)

High blood pressure; various gastro-intestinal disorders; heart failure; hardening of the arteries; gastritis; some forms of dyspepsia; peptic ulcer; exerting an anti-diarrheal effect in gastro-intestinal disease; producing certain desired results in amebic dysentery and some forms of cholera; fighting staphylococci which abound in boils and carbuncles; lessening the growing power of germs and impairing [6] their oxygen metabolism; waging war against types of germs which are not attacked by penicillin; cramping the style of paratyphoid bacteria; and remedying the effects of over-indulgence in alcoholic drinks.

Calcium, The Staff of Life (pages 34 and 35)

For high blood pressure.

(e) Alberty's Sabinol

Health Mysteries (page 28)

Dynamic Digests (pages 28 and 29)

For urinary discomforts; dull, achy feelings across the back and sharp pains in the kidneys; getting up frequently during the night; spots before the eyes; swelling of the feet, ankles, and lower limbs; dark circles beneath the eyes and puffiness; lack of vitality; favorably affecting the liver; promoting the flow of bile; remedying renal (kidney) troubles; for urinary discomforts and pain in kidneys; increasing the flow of urine and lessening its acidity; rendering the kidneys O. K. and flushing the kidneys; for inflammation of the kidneys, Bright's disease, dropsy, edema, tumor, stone, and tuberculosis.

Calcium, The Staff of Life (page 51)

For kidney diseases, bags under the eyes, frequent getting up nights, inflammation of the kidneys, Bright's Disease, dropsy, edema, abscess, tumor, kidney stone, tuberculosis, enuresis (bed-wetting), dysuria (painful urination); for increasing flow of urine and lessening its acidity.

(f) Alberty Phloxo B Tablets and Alberty's Phosphate Pellets

Health Mysteries (page 24)

Dynamic Digests (pages 8 and 28)

Preventing long-continued loss of sleep, disturbed sleep, premature old age, insanity; preventing the brain cells from losing their

recuperative powers and [7] their ability to eliminate the day's accumulation of waste products; preventing a depressed functioning throughout the whole system; preventing the nervous system from becoming adversely affected; inducing natural and healthful sleep; giving a soothing, relaxing effect; preventing nerves from being starved; for insomnia, nervousness, upset feeling, irritability; soothes and relaxes taut nerves; for highly nervous and excitable conditions; for inducing sleep to alcoholic addicts; and substituted for barbituric acid for sleeplessness.

Calcium, *The Staff of Life* (pages 52 and 53, 62 and 63, 65 and 66)

For nervousness, starved nerves, neurasthenis, nervous debility, worry, constant mental strain, acidosis, chronic diseases, sexual excesses, dysfunction of the ductless glands, anemia, Asthenia, insomnia, irritability, taut nerves, long continued abuse of the nervous system, worry, grief, too little sleep, mental exertion, over-indulgence in stimulants, degenerative diseases; for perfect development and maintenance of a normal, healthy brain and nervous system; to prevent inadequate sleep robbing the brain cells of their recuperative powers and ability to eliminate the day's accumulation of waste products; for asthenia; to remedy effects of faulty nutrition, toxemia, acidity, liver or urinary disorders and ailments that have been years in developing,

gastric ulcer, arthritis, rheumatism, kidney involvement, general run-down condition, malnutrition, acidity, hay fever, eczema, vomiting, toxic poisons, dormant liver, disturbed nervous system, kidneys unable to excrete poisons; for eliminating toxic poisons and [8] fixed acids and causing liver, kidneys, and other vital organs to function normally; for deficiency conditions where cells, tissues, and glands have been affected; for eczema, gastric ulcers, hay fever.

(g) Alberty's Riol Tablets

Dynamic Digests (pages 13 and 26)

For hay fever, sneezing, blowing, sniffing, allaying the distressing symptoms of hay fever, asthma, and other allergies.

Calcium, The Staff of Life (pages 54, 55 and 56)
For allergies; asthma; Vincent's Angina; gum diseases; hay fever; eczema; dry, scaling skin; ridged and splitting nails; dry, lifeless hair, profuse dandruff; certain kidney disorders.

(h) Alberty's Rico Tablets

Health Mysteries (page 29)

Dynamic Digests (pages 24 and 28)

Calcium, The Staff of Life (pages 60 and 61)

For arthritis; neuritis; rheumatism, including stiff, painful, swollen, and deformed joints and inflamed and painful muscles; preventing chronic sepsis; preventing urate deposits in muscles and mineral deposits in joints.

(i) Alberty Special Formula Tablets

Health Mysteries (page 15)

Dynamic Digests (page 13)

Calcium, The Staff of Life (page 67)

Feeding the glands of humans; stimulating the white blood corpuscles, acting as a brake on sugar metabolism; favorably affecting the adrenal glands and liver; stimulating regeneration of the blood and beneficial in the anemias; preventing many malfunctions; treating symptoms of the nervous and glandular systems of the body, and feeding the orchic (male) glands. [9]

(j) Alberty's Vitamin A (High Potency) Shark Liver Oil

Health Mysteries (page 14);

Dynamic Digests (page 22);

Calcium, The Staff of Life

(pages 63, 66, 73, 74, and 75)

For the relief of sinus discomfort, sinusitis; protection against colds; preventing infection of the sinuses, the respiratory tract, and the genito urinary system; treating acne; maintaining normal cell structure; giving health to the mucous membranes of the nose, sinuses, throat, bronchi, upper respiratory tract, eyes; providing normal denture formation of the teeth; healthful breast milk; building resistance to colds, infection of the eyes; preventing lack of energy; to benefit skin eruptions, dry skin, eczema, poor eyesight, inflamed membrane lining

of various parts of the body as nose, throat, lungs, urinary and reproductive organs; for sinusitis, colds, bad eyesight; to relieve tired, strained eyes; to prevent or remedy dry skin, impairment of teeth and bones, lack of energy.

(In Health Mysteries and
Dynamic Digests only)

Preventing cirrhosis of the liver and suffering from liver disease, preventing formation of kidney stones.

(In Health Mysteries only)

Preventing children's diseases and retarded growth.

(k) Alberty's Vi-C

Health Mysteries (page 23)

Dynamic Digests (page 12)

Calcium, The Staff of Life

(pages 63, 66 and 81)

For maintaining a healthy condition of the blood capillaries, teeth, bones, respiration, oxidation, and as an aid to healing, especially cuts and wounds; maintaining normal body chemistry; enabling certain cells and tissues to perform their functions normally and preventing untold misery; aiding in holding cells [10] and tissues together; aiding cells to perform their functions normally; preventing weak blood vessels, teeth from losing their normal structure and becoming diseased, gums from swelling and

bleeding, teeth from becoming loose and falling out, the skin from becoming dry and rough, and slight bruises from causing bleeding under the skin; preventing bad teeth; as an aid in almost every bodily activity; aiding clear reasoning, especially in time of mental strain; relieving pain after tonsil removal; relieving muscle cramps; to benefit hay fever, asthma, allergy; to insure a healthy condition of the blood capillaries, teeth, and bones; to insure proper respiration, oxidation, and healing.

(In Health Mysteries and
Dynamic Digests only)

Lowering the blood sugar level in diabetes, improving hair growth and coloring; providing nutrition to the thyro-adrenal system; aiding in formation of hemoglobin; enabling the bone marrow to produce the needed cell forms and the blood to take up oxygen from the lungs; preventing chronic fatigue and lowered resistance.

(1) Wheat Germ Oil

Dynamic Digests (page 20) and Calcium,
The Staff of Life (pages 82 and 83)

To prevent sterility; for enabling pregnant women to give birth to children more capable of acquiring intelligence than ordinary children; to permit functioning of the anterior pituitary gland; for affecting the development of the internal organs and sex glands, the quality and

quantity of mother's milk, growth and development and functioning of the thyroid gland [11] and pancreas; to benefit certain types of paralysis in humans; for ridding patients of primary fibrositis which cripples the muscles, muscular atrophy.

(In Dynamic Digests only)

For treating unfortunates suffering particularly from dementia praecox (insanity); improvement of all bodily functions of muscular vigor and mental reorganization of those suffering from dementia praecox, a form of insanity; for producing greater intelligence, quick, brilliant minds; livening the mental faculties; raising mental acumen.

- (m) Alberty's Vitamin B Complex Tablets with High-Potency B₁; Alberty's Vitamin B₁ with Supplementary Amounts of Other B Complex Factors

Health Mysteries (pages 12, 13 and 18);
Dynamic Digests (page 25); and Calcium, The
Staff of Life (page 78)

To prevent poor health; to benefit growth, appetite, digestion; for flatulence, headaches, dyspepsia, lack of stamina, chronic fatigue, nerves and intestinal activity, constipation; for improving the appetite and nutrition; gaining weight; toning the digestive tract; increasing endurance and energy and benefiting the glands; to benefit vital organs, nervous system, chronic arthritis, and some forms of neuritis; as a bene-

fit as a tonic; for giving a "lift" that carries one through "trying" days with energy to spare at the end of the day; enabling housewives, school teachers, salesmen, etc., to do their work with much less effort; preventing chronic ill health; for certain cases of heart disease and some cases of arthritis and neuritis; increasing the body's output of insulin and sugar tolerance with special interest to the diabetic; [12] to benefit mental cases and for improving the intelligence of school children; for benefiting totally unemployable men and women, some of whom may be insane.

(In Health Mysteries and Dynamic
Digests only)

Producing general fitness; affecting metabolism, growth, and development, correcting constipation, enabling one to recapture his vitality.

(In Health Mysteries only)

Stimulating; exerting a pep-up action; making the performance of ordinary tasks easier, shorter, and more bearable; preparing one against unexpected emergencies of illness or work; making one feel better and a little less tired at the end of the day; causing one to feel better and look younger; assuring against being let-down; acting as a safeguard against dragged-out, all-in, tired, nervous symptoms; and preventing suffering of the digestion, nerves, and intestinal activity; and providing general well-being.

- (n) Alberty's Lebara Pellets (Alberty's Lebara Plain and Alberty's No. 2)

Dynamic Digests (pages 7, 18 and 28), and Health Mysteries (pages 30 and 31), and Calcium, The Staff of Life (pages 56, 57, 62, 63, 65 and 66)

For bilious, sallow, or acid complexion; to produce a healthy, active liver, clear skin, bright eyes; for preventing excessive acid condition, keeping the liver cells active and healthy, enabling them to render harmless all poisons and acids received by the blood from the digestive tract; for toxic condition and other symptoms of a deranged liver; for preventing damaged and sluggish liver cells, destroying or transforming poisons or other harmful substances which [13] would otherwise kill one; preventing toxic wastes from entering the blood-stream; protecting the body from acidosis; preventing inability to digest fats, starches and sweets; preventing toxemia, acidity, bilious complexion, yellowish discoloration of the skin and whites of the eyeballs and frequently cases of intestinal indigestion. To remedy faulty nutrition, toxemia, acidity, liver or urinary disorders and ailments that have been years in developing, gastric ulcer, arthritis, rheumatism, kidney involvement, general run-down condition, malnutrition, acidity, hay fever, eczema, vomiting, toxic poisons, dormant liver, disturbed nervous

system, kidneys unable to excrete poisons; for eliminating toxic poisons and fixed acids, causing liver, kidneys, and other vital organs to function normally; for deficiency conditions where cells, tissues and glands have been affected. For rebuilding damaged liver cells, relieving symptoms of congestion of the liver, for eczema, gastric ulcers, hay fever, hives, acne, sinusitis.

(In Dynamic Digests only, pages 7, 18 and 28)

To remedy conditions of the liver which prevent toleration of fats, sweets, and starches; chronic indigestion due to disfunctions of the liver; abused liver which can no longer protect the body; overworked liver which is not able to prevent harmful toxic wastes and material from the bile entering the blood stream; toxic condition; yellowish discoloration of the skin and the whites of the eyes; jaundice; inactive liver and other liver ailments, such as biliousness and intestinal indigestion; malassimilation; dropsy; toxemia; [14] liver and gall-bladder disorders; prevention of certain liver and gall-bladder disorders which lead to the development of gallstones; disease of the gall bladder and stomach disorders resulting therefrom; prevention of allergy to citrus fruits and many other items of food; bilious, sallow or acid complexion; rendering the liver healthy and active thereby rendering the skin clear and healthy and the eyes clear and bright; keeping the liver

cells in an active, healthy condition so that they can render harmless all the poisons and acids that the blood receives from the digestive tract, thus preventing the individual from becoming toxic or developing other symptoms of a deranged liver; to repair damaged liver cells, increase flow of bile and relieve inflammation of liver.

(In Health Mysteries only, pages 30 and 31)

Activating the liver; below-par health; acidosis and resulting ill health, weakness, and premature old age; bringing about a normally healthy condition; filling one with vitality and the stamina allowed by one's age; preventing depletion of the fixed alkalis of the body in an effort to maintain blood alkalinity, and relieving acidosis which hampers cell reproduction, irritates the nerves, prevents proper assimilation of foods, destroys fats and retards elimination of waste products and toxic poisons and is present in rheumatism, skin disorders, mucous colitis, neuritis, kidney involvement, asthma and inflammation of the gall bladder. [15]

- (o) Cheno Herb Tea; Cheno Phytolacca Berry Juice Extract Tablets; Cheno Combination Tablets

Health Mysteries (page 2);

Dynamic Digests (pages 30 and 31)

Happy Figures by the Cheno Plan; and Reduce! Streamline Your Figure Follow the 5 Factor Cheno Plan

By the action of these products, cause a reduction of body weight apart from that which might be caused by the diet recommended.

(p) Tablets Pandora

Is There Hope That Graying Hair Can Be Restored? Read What Science Says—Pandora (leaflet);

Dynamic Digests (pages 10 and 11)

Postponing and stopping the graying of hair; preventing hair worries; restoring hair; restoring the natural color of hair; benefiting the entire system; preventing skin and tissues from becoming too dry; increasing blood volume, and stimulating the peripheral nerves; relieving hay fever; preventing destruction of hair follicles; and preventing listlessness and constant fatigue.

(q) Recal Tablets

Dynamic Digests (page 14);

Health Mysteries (pages 8 and 9)

Below-par conditions due to over-acid condition; preventing and correcting changes in the hormones including those secreted by the thyroid, parathyroids, testicles, ovaries, pituitary adrenals; lowered resistance to infections, ailments and disease, obviating destructive effects of excess acid on the cells of the body; upbuilding of the cells and tissues; obviating the effects of over-acid condition in hampering cell repro-

duction, lessening the blood's capacity to carry oxygen and irritating the nerves; [16] assisting complete assimilation of fats and elimination of toxic poisons and other waste products thus preventing neuritis, rheumatism, gout, kidney involvement, asthma, heart trouble, inflammation of the gall bladder, ulcers and abscesses; favorably affecting all forms of disease, acute and chronic; preventing malfunctioning of the nervous, muscular, and digestive systems.

(In Health Mysteries only)

Maintaining the chemical balance of the fluids of the thyroid gland; preventing and correcting nervousness; lack of energy; and preventing signs of early aging.

(r) Alberty's Vio-Min Vitamin-Mineral Tablets

Health Mysteries (page 10)

Building strength and resistance to disease; preventing degeneration of body cells, depletion of the reserves of the body, suffering of the glands, premature old age, haggard, dopey feeling, constant tiredness, lack of pep or energy to do more than drag around from day to day; causing the cells to really begin to live; rendering one alive, vital, gloriously healthy to the very fingertips; and putting one in the pink of condition, thus automatically increasing the body resistance to high up in the safety zone.

(s) Alberty's R-Gon Tablets

Dynamic Digests (page 21)

Preventing stomach ulcers; impairment of the nervous system and digestion caused by worry, anger, strain, emotional stress and long hours of fatiguing work; protecting the stomach from the ill effects of alcohol and irritating foods; gnawing pain of the stomach; and perforation peritonitis. [17]

(t) Alberty's Laxative Blend Tea

Dynamic Digests (page 13);

Health Mysteries (page 15)

Correcting a tired, lazy, sluggish feeling.

(u) Alberty's Ca-Mo Pellets

Calcium, The Staff of Life (page 45)

For teething children, as a preferred source of calcium.

(v) Alberty's Vitamin A and G Perles

Calcium, The Staff of Life (page 76)

For preventing eye disease and cataracts and to aid vision.

(w) Alberty's Rego

Calcium, The Staff of Life (page 72)

For preventing colds, for the relief of common and "grippy" colds, to benefit sneezing, chilly, watery eyes, aching muscles, headache, raw-irritated throat.

5. In addition, said defendants cause to be disseminated and sponsored from time to time, information and advice relative to the alleged merits of such articles of drug by the use of demonstrators at various cities throughout the United States, generally in so-called "Health Food" stores, which information and advice is to the effect that such articles are effective for the purposes set forth in such booklets and leaflets.

6. A typical scheme of distribution and method adopted by said defendants to sell and market such articles of drug has been to enter into an oral agreement with the operator of a so-called "Health Food" store. The defendants ship their products directly to the store where the products are sold to the public. The leaflets and booklets are shipped by defendants from Hollywood, California, to an individual or distributing organization designated by the storekeeper. The local individual or organization, or in some instances the defendants themselves, mail said leaflets and booklets to persons whose addresses are supplied by the storekeeper. When the supply of literature is depleted, the storekeeper notifies defendants who ship a new supply of said leaflets and booklets directly to the local repository. From time to time [18] these storekeepers have permitted prospective customers to read such literature while present in the store. Should the customer purchase an Alberty product or indicate any interest in these products, his name and address are solicited by the storekeeper and copies of said leaflets and

booklets are mailed him from the local repository. Demonstrators sent by defendants make the rounds of these stores extolling the virtues of Albery Products, making substantially the same representations as do the booklets with respect to these articles. The demonstrator in some cases displays the booklets and leaflets and permits them to be read in the store. Again the names and addresses of those interested are solicited and the booklets are sent out through the mail.

7. Said articles of drug consist for the most part of dried vegetables, cereals, vitamins, and minerals in various combinations. The composition of said articles is such that they will not be effective, alone or in combination as represented in the leaflets and booklets, to fulfill the promises of benefit made for them in the manner and by the means hereinbefore outlined, or in any other manner.

8. The defendants from time to time have been and are now introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce at Hollywood, California, in violation of Section 301(a) of the Act [21 U.S.C. 331(a)] the above-named articles of drug. Further, the defendants have been doing or have caused to be done and are doing or causing to be done certain acts with respect to said articles of drug, while said articles are being held for sale after shipment in interstate commerce, which results in said articles being misbranded in violation of said Section 301(k) of the Act [21 U.S.C. 331(k)].

9. All of said articles when introduced into interstate commerce are drugs within the meaning of Section 201(g) of said Act [21 U.S.C. 321(g)], and have been and are misbranded when introduced into interstate commerce within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)], in that their labelings are false and misleading since said articles are not efficacious for the prevention, treatment, or cure of the diseases or conditions for which they are respectively represented or suggested in said labeling. [19]

10. At all times, the aforesaid articles of drug, when introduced into interstate commerce, have been and are now misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352 (f) (1)], in that their labelings fail to bear adequate directions for use for the purposes and conditions for which they are intended.

11. Defendants have caused and are causing certain printed and graphic matter, in addition to the leaflets and booklets enumerated in paragraph 4, to be used with and to accompany the aforesaid articles of drug while said articles were and are held for sale after shipment in interstate commerce, which act results in said articles being misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)], in that said printed and graphic matter contains false and misleading statements similar to those specified in paragraph 4 regarding the nutritional and therapeutic effects of said articles, in violation of Section 301(k) of the Act [21 U.S.C. 331(k)].

12. Defendants have also caused and are causing certain oral representations to be made by demonstrators regarding the therapeutic effect of said articles of drug while said articles were held for sale after shipment in interstate commerce, which act results in said articles of drug being misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)], in that the labelings of said articles of drug failed to bear adequate directions for use for the purposes for which they were recommended by such oral representations sponsored by said defendants, while said articles were held for sale after shipment in interstate commerce, in violation of section 301(k) of the Act [21 U.S.C. 331(k)].

13. The defendants are well aware that their activities are violative of the Act. Under the Federal Food and Drugs Act of 1906 there are at least 12 notices of judgment reporting termination of seizure cases against some of these products. The defendant Ada J. Alberty was twice convicted under that Act. Under the Federal Food, Drug and Cosmetic Act of 1938, six seizure actions against Alberty Products have been terminated in favor of the Government, and several others are now pending; conviction of defendant Ada J. Alberty in this Court was reversed by the Court of Appeals in *Albert v. United States*, 159 F. (2d) [20] 278, on grounds of statutory construction later held invalid by the Supreme Court in two unrelated cases, Kor-

del v. United States, 69 S. Ct. 106, and Urbuteit v. United States, 69 S. Ct. 112.

14. The plaintiff is informed and believes that unless restrained by the Court, the defendants will continue to introduce and deliver for introduction into interstate commerce the said articles of drug misbranded in the manner aforesaid and will continue to do those acts, while holding said drugs for sale after shipment in interstate commerce which result in misbranding in the manner aforesaid.

Wherefore, plaintiff prays:

That the defendants, Alberty Food Products, a partnership, and Ada J. Alberty and Kenneth Hackworth, individuals, and each and all of their officers, agents, representatives, servants, employees, and attorneys, and all persons in active concert or participation with any of them, be perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and from doing or causing to be done any act with respect to said articles while held for sale after shipment in interstate commerce which act results in such articles being misbranded, in violation of Section 301(a) and (k) of said Act [21 U.S.C. 331(a) and (k)], articles of drug, hereinbefore enumerated, or by any other designation, or any similar drug, misbranded within the meaning of sections 502(a) and 502(f)(1) [21 U.S.C. 352(a) and 352(f)(1)].

That an order be made and entered herein directing the defendants to show cause, at a time and place to be designated in such order, why they should not be enjoined and restrained as herein prayed during the pendency of this action; that upon the hearing of said order to show cause, a preliminary injunction be granted restraining the defendants as herein prayed during the pendency of this action; that the plaintiff be given judgment for its costs herein and for such other and further relief as to the court may seem just and proper.

/s/ MAX F. DEUTZ,

Assistant U. S. Attorney.

[Endorsed]: Filed October 7, 1949. [21]

[Title of District Court and Cause.]

ORDER DISCHARGING ORDER TO SHOW
CAUSE RE PRELIMINARY INJUNCTION

The above-entitled matter having come on regularly for hearing before the Honorable William C. Mathes on November 28, 1949, the plaintiff appearing by Ernest A. Tolin, United States Attorney, Clyde C. Downing and Max F. Deutz, Assistant United States Attorneys, and the defendants appearing by their counsel, William V. O'Connor; the plaintiff having moved that the Order to Show Cause re Preliminary Injunction be discharged without prejudice, and good cause appearing therefor.

Now Therefore, It is Hereby Ordered, Adjudged and Decreed that the Order to Show Cause re Preliminary Injunction heretofore issued on October 7, 1949, be discharged without prejudice.

Done in Open Court Nov. 28, 1949.

/s/ WM. C. MATHES,
United States District Judge.

Submitted by:

/s/ MAX F. DEUTZ.

Approved as to Form:

/s/ WILLIAM V. O'CONNOR.

[Endorsed]: Filed December 1, 1949. [26]

[Title of District Court and Cause.]

ORDER FOR PRE-TRIAL PROCEEDINGS

Good cause appearing therefor, upon the Court's own motion it is Ordered:

[1] That this case be placed on calendar for pre-trial hearing in Court Room No. 2 of this Court at 10 o'clock on January 23, 1950, pursuant to Rule 16 of the Federal Rules of Civil Procedure, and local rules 9, 10 and 11 of this Court; and unless excused for good cause, each party appearing in the action shall be represented at all pre-trial hearings, and at all meetings held pursuant to [2] hereof,

by the attorney who is to conduct the trial on behalf of such party.*

[2] Not later than fifteen days in advance of the pre-trial hearing, the attorneys for the parties appearing in the case shall meet at a mutually convenient time and place, and:

[a] exhibit to opposing counsel all documents (other than those to be used for impeachment) intended to be offered at the trial by each party represented;

[b] formulate a concise statement of the facts involved, as claimed by each party; and

[c] ascertain [i] which facts are to be admitted by all or any of the parties for the purposes of the trial, [ii] which facts, although not admitted, are not expected to be contested at the trial, as counsel are presently advised, and [iii] which issues of fact the respective parties intend to litigate upon the trial. [27]

[3] Not later than ten days in advance of the pre-trial hearing, each party appearing shall serve and file with the Clerk a "Memorandum of Law" containing a brief statement of the points of law, and a citation of the authorities in support of each point, upon which such party intends to rely at the trial.

[4] Not later than five days in advance of the pre-trial hearing, the parties appearing shall file

[*In many cases time is saved if the parties also attend.]

with the Clerk a "Pre-Trial Stipulation," executed jointly, and containing:

[a] a "Stipulation of Facts" setting forth a detailed recital of all facts involved which are conceded by the parties;

[b] a "Schedule of Exhibits" comprising a list of all documents exhibited by each party at the meeting or meetings held pursuant to [2] above, with a description of each document sufficient for identification, and a statement of all admissions by and all issues between any of the parties as to the genuineness thereof, the due execution thereof, and the truth of relevant matters of fact set forth therein;

[c] a Statement of any objection reserved by any party to the admissibility of any fact covered by stipulation;

[d] a Statement limiting the effect of admissions of fact as provided by Rule 36(b) F.R.C.P., if desired by any party; and

[e] a Statement setting forth all alleged facts which any party is unable to concede but does not, as presently advised, intend to contest at the trial by evidence to the contrary.

[5] Not later than three days in advance of the pre-trial hearing, each party appearing shall serve and file with the Clerk a "Pre-Trial Statement of Issues" containing:

[a] a concise recital of all ultimate facts which such party contends remain at issue to be litigated upon the trial;

[b] a statement of each issue of law (including questions of evidence and procedure) expected to arise at the trial, as to which such party seeks a ruling of the Court, predicated upon either an agreed or an assumed state of facts, in advance of the trial;

[c] if the case be one in which the Court may award a reasonable sum to the prevailing party for attorneys' fees, the present estimate as to the maximum amount to be requested in the event such party prevails upon the trial;

[d] a statement of the position of such party with respect to all other matters referred to in Rule 16 F.R.C.P., which are deemed applicable to the case; and

[e] any other stipulations or suggestions for the assistance of the Court, including an estimate of counsel as to the probable duration of the trial. [28]

[6] At the pre-trial hearing each party shall present to the Court, to be marked for identification, all documents (other than those to be used for impeachment) intended to be offered at the trial by such party; and the Court will then consider:

[a] the stipulations, statements and memorandums filed pursuant to [3], [4] and [5] above;

[b] all documents relied upon by the respective parties;

[c] all matters referred to in Rule 16, F.R.C.P., which may be applicable to the case;

[d] all motions and other proceedings then pending under Rules 12, 33-37, or 56 F.R.C.P.;

[e] any other matters which may be presented relative to parties, process, pleading or proof, with a view to simplifying the issues and bringing about a just, speedy and inexpensive determination of the action.

[7] Upon conclusion of the pre-trial hearing, the Court will set the case for trial* and enter such further orders as the status of the case may require.

[8] The memorandum of points and authorities required pursuant to [3] may be considered as compliance with local rule 12.

[9] All papers called for by this order shall be filed in duplicate and in the form required by local rule 4.

It Is Further Ordered that the Clerk this day serve this order by United States mail upon all parties appearing in the cause.

December 2, 1949.

/s/ WM. C. MATHES,

United States District Judge.

[Form Civ. 21]

[Mathes, J.]

[Rev. 5, 8/49.]

[Endorsed]: Filed December 2, 1949. [29]

[*This case will not be called for setting pursuant to local rule 3.]

[Title of District Court and Cause.]

PRE-TRIAL STIPULATION

(A) Stipulation of Facts Conceded by the Parties

(1) All of the facts alleged in paragraphs 1, 2, 3 and 13 of the Amended Complaint for Injunction filed in this case are admitted; except that defendants deny that they were aware their activities are violative of the Act.

(2) All of defendants' products referred to in the Amended Complaint for Injunction are drugs and are shipped interstate by the defendants. An additional drug which defendants ship interstate is Cheno Phytolacca Berry Juice Extract Tablets, and it is agreed that the effect, if any, of this drug in weight reduction, when taken as directed in the label, is identical with the effect of Cheno Preparation of Phytolacca Berry Juice in weight reduction, when the latter drug is taken as directed in the label. See Government's Exhibit 20 for the labels of both products.

(3) The composition of each of the 10 products enumerated below is [30] the same in the present case as the composition of the same 10 products involved in the case of *U. S. v. 12 Packages * * * Alberty Food, etc.*, which originated in the U. S. District Court for the District of Columbia as District No. 2696 and was transferred for trial to the U. S. District Court for the Northern District of California, where it was assigned Docket No. 23457-W (See Government's Exhibit 36):

Alberty Food

Instant Alberty Food

Alberty's Vegetable Compound Capsules

Alberty's Ca-Mo Pellets

Alberty's Phosphate Pellets

Alberty's Lebara Pellets

Alberty's Laxative Blend

Cheno Herb Tea

Cheno Combination Tablets

Cheno Preparation of Phytolacca Berry Juice.

(4) Defendants ship all of their products in interstate commerce to health food retail outlets and intend to continue so shipping these products. Defendants also ship these products interstate direct to ultimate consumers in response to mail orders from such persons.

(5) The various items of literature referred to in paragraph 4 of the Amended Complaint represent and suggest that defendants' products are useful as specified in said paragraph, but defendants expressly object to the admissibility of such evidence except insofar as it relates to the booklets "Calcium—The Staff of Life" and "Happy Figures by the Cheno Plan—The 5-Factor Reducing Plan."

(6) The composition of each of defendants' products is as declared in the labels which comprise Government's Exhibits 1-29, inclusive, with the following qualifications:

(a) An amplified statement as to the quantitative formulae of some of these products is contained in Government's Exhibits 38-44, inclusive.

(b) The weight of an Alberty Vegetable Compound capsule [31] is 10 grains.

(c) The weight of an Alberty's Sabinol pellet is 1.1 grains.

(d) The weight of a Ri-Co tablet is 2.41 grains.

(e) The weight of a Lebara No. 2 pellet is 1.1 grains.

(7) During the past 25 years, the defendants have used literature similar to that identified as Government's Exhibits 29-35, and many other items of literature, in the promotion of the products involved in this case:

(a) Defendants have shipped their products and their literature interstate simultaneously from the same point of origin to the same retail outlet.

(b) Defendants have made separate interstate shipments of their products and their literature from the same point of origin to the same retail outlet.

(c) Defendants have made interstate shipments of their products from one State and of their literature from another State, both consigned to the same retail outlet.

(d) Defendants have made separate interstate shipments of their products and their literature from the same point of origin, the products being consigned to a retail outlet, and the literature being consigned to a mailing agency which in turn mailed the literature to persons whose names and addresses were fur-

nished such agency by the retail outlet and by the defendants.

(e) Defendants have made interstate shipments of their products from one State to a retail outlet, and interstate shipments of their literature from another State to a mailing agency which in turn mailed the literature to persons whose names and addresses were furnished such agency by the retail outlet and by the defendants.

(8) In promoting the interstate sale of the products here involved, defendants are currently using the literature which is identified as Government's Exhibits 30 and 35, though the Government reserves the right to introduce evidence regarding the defendants' current interstate use of the literature identified as Government's Exhibits 31-34, inclusive.

(9) Defendants are currently distributing interstate in the following [32] ways the literature identified as Government's Exhibits 30 and 35:

(a) Defendants obtain the names and addresses of prospective customers from the retail outlets to which they sell their products. Defendants mail said literature to said prospective customers, and on such literature defendants print the name and address of the retail outlet that furnished such names and addresses.

(b) Defendants also obtain the names and addresses of prospective customers from demonstrators who are hired by the defendants to work in retail outlets and there promote the

sale of defendants' products. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

(c) Defendants also obtain the names and addresses of prospective customers when individuals write in to the defendants for literature or to submit mail orders. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

(d) [The Government reserves the right to introduce evidence regarding other current methods of interstate distribution used by defendants.]

(10) Defendants utilize newspaper and magazine advertising in promoting the interstate sale of their products. In running such advertisements, it is defendants' practice to furnish their retail outlets with advertising mats. The retail outlets then arrange to have the advertisements appear in newspapers and magazines, and the defendants pay part or all of the costs of such advertisements as the case may be. The representations which the defendants make for their products in these advertisements are substantially the same as the representations which they make for their products in their literature.

(11) Defendants ship all of their products and literature from Hollywood, Calif.

(B) Schedule of Exhibits

Government's Exhibits—1-29, Inclusive—Labels

These Exhibits are the genuine labels of the products which [33] defendants are currently shipping interstate. These Exhibits are admissible in evidence without any objection.

30-35, Inclusive—Literature

These Exhibits are genuine examples of literature which defendants have shipped interstate. Defendants assert that they are currently shipping interstate the literature which comprises Government's Exhibits 30 and 35 only, but defendants deny that they are currently shipping interstate the literature which comprises Government's Exhibits 31-34, inclusive. Defendants object to the admission in evidence of Government's Exhibits 30-35, inclusive, on the ground that such literature is not "labeling" within the meaning of 21 U.S.C. 321(m). There is no objection to the admission of these Exhibits in evidence for the restricted purpose of showing the conditions for which defendants offer the products involved.

36—Certified Copy of Pleadings, Findings,
Conclusions, and Orders in 1942 Trial

This Exhibit is genuine and has been duly executed. It may be admitted in evidence without any objection.

37—Certified Copy of Pleadings, Findings, Conclusions, Order, Opinion, and Notice of Appeal in
1949 Trial

This Exhibit is genuine and has been duly executed. It may be admitted in evidence without any objection.

38-44, Inclusive—Quantitative Formulae

These formulae are genuine and they supplement the composition statements as declared on the labels of Government's Exhibits 2, 11, 21, 22, 23, 25, and 26;

Government's Exhibits 38-44, inclusive, each bears a reference to the particular Government Exhibit that contains the label of the product involved. Government's Exhibits 38-44, inclusive, may be admitted in evidence without any objection. [34]

45-132, Inclusive—Booklets, Leaflets,
Advertisements, etc.

These Exhibits are genuine examples of literature and advertisements which defendants have used in the past. Defendants object to their being admitted in evidence.

ERNEST A. TOLIN,
United States Attorney;

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division;

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ WILLIAM V. O'CONNOR,
Attorney for Defendants.

It Is so Ordered this ... day of, 1950.

.....,

United States District Judge.

[Endorsed]: Filed February 15, 1950. [35]

[Title of District Court and Cause.]

PRE-TRIAL STATMENT OF ISSUES
AS STIPULATED

The parties to this proceeding are agreed that there remain only three ultimate issues in this case:

(1) Is the literature, which the defendants use in promoting the interstate sale of their drugs, "labeling" within the meaning of 21 U.S.C. 321(m) ?

(2) If this literature is "labeling," is this labeling false and misleading so as to cause the drugs which defendants sell to be misbranded within the meaning of 21 U.S.C. 352(a) ?

(3) Does the labeling of defendants' 29 articles of drug, which are involved in this case, fail to bear adequate directions for use, thereby causing said drugs to be misbranded within the meaning of 21 U.S.C. 352(f)(1) ?

The Pre-Trial Stipulation provides a sufficient factual basis for the [36] Court to determine the first and third issues without any additional evidence.

The Government contends that the Pre-Trial Stipulation provides sufficient factual basis for the Court to decide a portion of the second issue without further evidence. This contention is predicated upon the claim that the 1942 trial (Government's Exhibit 36) in res judicata here with respect to 10 of the drugs here involved. The defendants contend that res judicata is not applicable and assert that the therapeutic claims that were involved in the 1942 case are different from the therapeutic claims involved in the instant case. It is the Government's position that the therapeutic claims are essentially the same.

It is estimated that the trial of this case, with respect to the remaining portion of the second issue, will consume approximately six days.

Respectfully submitted,

ERNEST A. TOLIN,
United States Attorney;

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division;

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ WILLIAM V. O'CONNOR,
Attorney for Defendants.

[Endorsed]: Filed February 16, 1950. [37]

[Title of District Court and Cause.]

MEMORANDUM TO COUNSEL

As to the questions of law with respect to which the parties seek a ruling in advance of trial pursuant to paragraph 5(b) of the "Order for Pre-trial Proceedings" herein, the court will rule upon the trial, in the absence of controlling precedent to the contrary:

(1) that Exhibit 30 [See paragraph 8 of Pre-trial Stipulation filed February 15, 1950], which distributed by the means, in the manner and for the purposes described in paragraph 9 of the pre-trial stipulation filed February 15, 1950, cannot be considered as "accompanying" [21 U.S.C. § 321(m) (2)], in "interstate commerce" [21 U.S.C. §§ 331(a), 321(b)], any "drug" [21 U.S.C. § 321(g)] prescribed, recommended or suggested in the exhibit as being "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of [38] disease in man or other animals" [21 U.S.C. § 321(g) (2)], or "intended to affect the structure or any function of the body of man or other animals" [21 U.S.C. § 321(g) (3)]; and the exhibit does not therefore comprise a portion of the "labeling" of any such drug within the meaning of 21 U.S.C. § 321(m) [See 21 U.S.C. § 321(k), (1); cf. *Kordell v. United States*, 335 U. S. 345, 346, 348 (1948); *Urbuteit v. United States*, 335 U. S. 355, 357-358 (1948)];

(2) that Exhibit 35 [See paragraph 8 of the Pre-trial Stipulation filed February 15, 1950], when

distributed by the means, in the manner and for the purpose described in paragraph 9 of the pre-trial stipulation filed February 15, 1950, cannot be considered as “accompanying” [21 U.S.C. § 321(m) (2)], in “interstate commerce” [21 U.S.C. §§ 331 (a), 321(b)], any “drug” [21 U.S.C. § 321(g)] prescribed, recommended or suggested in the exhibit as being “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” [21 U.S.C. § 321(g) (2)], or “intended to affect the structure or any function of the body of man or other animals” [21 U.S.C. § 321(g) (3)]; and the exhibit does not therefore comprise a portion of the “labeling” of any such drug within the meaning of 21 U.S.C. § 321(m) [See 21 U.S.C. § 321(k), (1); cf. *Kordell v. United States*, 335 U. S. 345, 346-348 (1948); *Urbuteit v. United States*, 335 U. S. 335, 357-358 (1948)];

(3) that the “labeling” [21 U.S.C. § 321(m) (1)]—which appears to comprise only the “labels” [21 U.S.C. § 321(k), (1); Exhibits 1 to 29 inclusive]—of the 29 “drugs” [21 U.S.C. § 321(g); paragraph 2 of Pre-trial Stipulation filed February 15, 1950] involved in this action, does not bear “adequate directions for use” within the meaning of 21 U.S.C. § 352(f) (1), in that such “labeling” as to each [39] “drug” fails to reveal the dosage or the frequency or duration of taking prescribed, recommended or suggested in connection with the diseases or conditions of the body for which such drug is held out to the public [See U.S.C. §§ 352

(j), 321(n), 371(a), 352(f); 21 Code Fed. Regs. § 1.106 (1949); *Colgrove v. United States*, 176 F.2d 614, 616 (9th Cir. 1949); *United States v. Various Quantities * * ** "Instant Alberty Food," 83 F. Supp. 882, 885 (D.C.D.C. 1949)]; and each such "drug" must therefore be held to be "misbranded" within the meaning of 21 U.S.C. § 352(f) (1).

A ruling on the issue of res judicata as to the ten drugs involved in this action which were the subject of seizure and condemnation in the United States District Court for the Northern District of California in case No. 23457-W, entitled "*United States v. 12 Packages * * * Alberty Food, etc.*" [See Exhibit 36; paragraph 3 of Pre-trial Stipulation filed February 15, 1950], will be deferred, in view of counsel's assurance [See Defts.' Memorandum of Law filed February 17, 1950, p. 6, lines 1-14] that the claims now asserted by defendants for the ten drugs in question are "different therapeutic claims * * * from those asserted and maintained when these articles were manufactured and distributed in 1942" [cf. *George H. Lee Co. v. United States*, 41 F.2d 460, 462 (9th Cir. 1930)].

It Is Ordered that the Clerk this day serve copies of this memorandum by United States mail on the attorneys for the parties appearing in this cause.

July 13, 1950.

/s/ WM. C. MATHES,

United States District Judge.

[Endorsed]: Filed July 13, 1950. [40]

[Title of District Court and Cause.]

MOTION FOR SUMMARY JUDGMENT
AND NOTICE OF MOTION

Motion for Summary Judgment

Comes Now the plaintiff United States of America by and through its attorneys, Ernest A. Tolin, United States Attorney for the Southern District of California; Clyde C. Downing and Max F. Deutz, Assistant United States Attorneys, and moves the court that it enter, pursuant to Rule 56 of the Federal Rules of Civil Procedure, a summary judgment in its favor granting an injunction against the defendants herein as prayed for in the Amended Complaint on the following grounds and for the following reasons:

I.

That in its Memorandum to Counsel dated July 13, 1950, this Court has ruled that the labeling of the 29 drugs involved in this cause, as represented by Exhibits 1 to 29, inclusive, does not bear "adequate directions for use" within the meaning of 21 U.S.C. § 352(f) (1), in that such "labeling" as to each "drug" fails to reveal the dosage or the frequency or duration of taking prescribed, [41] recommended or suggested in connection with the diseases or conditions of the body for which such drug is held out to the public; and that each such "drug" is therefore "misbranded" within the meaning of 21 U.S.C. § 352(f) (1).

II.

That there are no facts in dispute with respect to that portion of the Amended Complaint which seeks an injunction under 21 U.S.C. § 332(a) to restrain defendants from violating 21 U.S.C. § 331 (a) through the continued interstate shipment of drugs that are misbranded in violation of 21 U.S.C. § 352(f) (1).

III.

That in view of this Court's rulings of July 13, 1950, it appears that the United States is entitled to judgment as a matter of law and that therefore further trial of this case would be futile.

This motion is based and will be presented upon the records and files herein, all of the pleadings and admissions filed by the respective parties hereto, including the Pre-trial Stipulation, the Exhibits admitted in evidence, the Affidavit of Ada J. Alberty, in response to the Interrogatories of the plaintiff, upon the Memorandum to Counsel, and upon the Memorandum of Points and Authorities attached hereto.

Dated July 19th, 1950.

ERNEST A. TOLIN,

United States Attorney;

CLYDE C. DOWNING,

Assistant U. S. Attorney,

Chief, Civil Division;

/s/ MAX F. DEUTZ,

Assistant U. S. Attorney;

Attorneys for Plaintiff.

Notice of Motion for Summary Judgment

To Alberty Food Products, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, Helen Hackworth, and to Willian V. O'Connor, Their Attorney:

You and Each of You, will please take notice that the plaintiff, the United States of America, by and through the undersigned, will bring the above and foregoing motion on for hearing before the above-entitled court in the courtroom of the Honorable Wm. C. Mathes, United States District Judge, in the United States Post Office and Court House Building, Los Angeles, California, on Monday, the 31st day of July, 1950, at the hour of 10 o'clock, a.m., on that day or as soon thereafter as counsel can be heard.

Dated at Los Angeles, California, this 19th day of July, 1950.

ERNEST A. TOLIN,
United States Attorney;

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division;

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

Receipt of copy acknowledged.

[Endorsed]: Filed July 19, 1950. [43]

[Title of District Court and Cause.]

STATEMENT OF FACTS THAT ARE MATERIAL AND EXIST WITHOUT CONTROVERSY

Comes Now the plaintiff United States of America by and through its attorneys, Ernest A. Tolin, United States Attorney for the Southern District of California; Clyde C. Downing and Max F. Deutz, Assistant United States Attorneys, and files a statement of the facts that are material and exist without substantial controversy, pursuant to Local Rule 3(d) (2) and in support of its Motion for Summary Judgment:

(1) All of the products in this cause are drugs and are shipped interstate by the defendants. [Pre-Trial Stipulation, page 1, lines 24-25, and page 2, lines 21-26.]

(2) The "labels" of these drugs are before the Court by stipulation at the Pre-Trial hearing. [Plaintiff's Exhibits 1-29.]

(3) Under the Court's ruling of July 13, 1950, the "labeling" of defendants' drugs consists only of the "labels" identified as Plaintiff's Exhibits 1-29. [47]

(4) Said "labeling," on its face, shows a failure to state the diseases and conditions of the body for

which said drugs are offered to the public by the defendants.

Dated July 19th, 1950.

Respectfully submitted,

ERNEST A. TOLIN,

United States Attorney;

CLYDE C. DOWNING,

Assistant U. S. Attorney,

Chief, Civil Division;

/s/ MAX F. DEUTZ,

Assistant U. S. Attorney,

Attorneys for Plaintiff.

Copy received.

[Endorsed]: Filed July 19, 1950. [48]

[Title of District Court and Cause.]

SUPPLEMENTAL STIPULATION

It Is Hereby Stipulated by and between all of the parties to this proceeding, through their respective attorneys, that, for the purposes of the pending Motion for Summary Judgment only, Government's Exhibits 1 through 35, inclusive, comprise all of the literature and labels relevant to this case; the use

of said literature and labels by the defendants being as described in the Pre-Trial Stipulation.

ERNEST A. TOLIN,
United States Attorney;

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division;

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ WILLIAM V. O'CONNOR,
Attorney for Defendants.

[Endorsed]: Filed September 8, 1950. [50]

[Title of District Court and Cause.]

NOTICE OF HEARING OF MOTION
FOR SUMMARY JUDGMENT

To Alberty Food Products, a Partnership, and to
O'Connor & O'Connor, 530 West 6th Street,
Los Angeles 14, California, Their Attorneys:

You, and each of you, will please take notice that the hearing on the Motion for Summary Judgment, heretofore called on the calendar of the Honorable William C. Mathes, in the United States Post Office & Court House, Los Angeles, California, at 2:00 p.m., on February 5, 1951, has been continued for hearing in the same Court on Monday, March 5, 1951, at the hour of 2:00 p.m., or as soon thereafter

as counsel can be heard, and that the Court by an oral order of February 5, 1951, has instructed counsel to be present at that time.

Dated February 8th, 1951.

ERNEST A. TOLIN,
United States Attorney;

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division;

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

Affidavit of Service by Mail attached.

[Endorsed]: Filed February 8, 1951. [51]

[Title of District Court and Cause]

MEMORANDUM OF DECISION

The Government invokes the jurisdiction of this Court under § 302(a) of the Federal Food, Drug and Cosmetic Act [52 Stat. 1043, 21 U.S.C. § 332(a)] to enjoin alleged violations by defendants of § 301 which prohibits “introduction . . . into interstate commerce of any . . . drug . . . that is . . . misbranded” [21 U.S.C. § 331(a)]. [53]

The amended complaint for injunction alleges inter alia:

That defendants are “the manufacturers,

packers and distributors of certain articles of drug . . .”;

That “For some years, defendants have introduced said articles of . . . drug into interstate commerce, and have caused said articles to be accompanied by various leaflets and booklets when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce. Said leaflets and booklets are entitled ‘Calcium, The Staff of Life’ [Exhibit 30]; ‘Dynamic Digests’ [Exhibit 31]; ‘Is There Hope That Graying Hair Can Be Restored? Read What Science Says—Pandora’ [Exhibit 32]; ‘Health Mysteries’ [Exhibit 33]; ‘Reduce! Streamline Your Figure—Follow the 5 Factor Cheno Plan’ [Exhibit 34]; ‘Happy Figures by the Cheno Plan’ [Exhibit 35]. Each of these booklets and leaflets relates to one or more of the above-mentioned articles of drug . . .”;

That “At all times, the aforesaid articles of drug, when introduced into interstate commerce, have been and are now misbranded within the meaning of [54] section 502(f) (1) of the Act [21 U.S.C. § 352(f) (1)], in that their labelings fail to bear adequate directions for use for the purposes and conditions for which they are intended.”

At pre-trial hearing the parties stipulated:

(1) That “defendants’ products referred to in the Amended Complaint for Injunction are drugs and are shipped interstate by the defendants.”

(2) That “Defendants ship all of their products in interstate commerce to health food retail outlets and intend to continue so shipping these products. Defendants also ship these products interstate direct to ultimate consumers in response to mail orders from such persons.”

(3) That “Defendants are currently distributing [the above-mentioned literature] interstate in the following ways . . . :

“(a) Defendants obtain the names and addresses of prospective customers from the retail outlets to which they sell their products. Defendants mail said literature to said prospective customers, and on such literature defendants print the name and address of the retail outlet that furnished such names and addresses. [55]

“(b) Defendants also obtain the names and addresses of prospective customers from demonstrators who are hired by the defendants to work in retail outlets and there promote the sale of defendants’ products. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

“(c) Defendants also obtain the names and addresses of prospective customers when individuals write in to the defendants for Literature or to submit mail orders. Defendants mail the aforesaid literature to said prospective cus-

tomers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.”

Section 201 of the Act provides in part that:

“(a) The term ‘label’ means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement . . . that any word, statement, or other information appear on the label shall not be [56] considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * *

“(1) The term ‘immediate container’ does not include package liners.

“(m) The term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers, or wrappers, or (2) accompanying such article.”

The parties have stipulated to the identity and content of the label used “upon the immediate container” of each article, and further that such “label” [21 U.S.C. § 321(k), (1)] constitutes the entire “labeling” [21 U.S.C. § 321(m)] as to each article, unless the above-mentioned “literature” is to be considered as “accompanying such article” in interstate commerce within the meaning of

§ 201(m) (2) of the Act [21 U. S. C. § 321(m) (2)].

Based upon the facts established by the pleadings and the pre-trial stipulations, the Government has moved for summary judgment upon the ground: "That there are no facts [57] in dispute with respect to that portion of the Amended Complaint which seeks an injunction under 21 U.S.C. § 332(a) to restrain defendants from violating 21 U.S.C. § 331(a) through the continued interstate shipment of drugs that are misbranded in violation of 21 U.S.C. § 352(f) (1)," which provides that: "A drug . . . shall be deemed to be misbranded . . . (f) unless its labeling bears (1) adequate directions for use. . . ."

In order to determine whether the labeling as to any "drug" [21 U.S.C. § 321(g)] bears "adequate directions for use" within the meaning of the Act it is necessary of course first to ascertain what comprises "its labeling." Section 201(m) declares that: "The term 'labeling' means all labels [see 21 U.S.C. § 321(k), (1)] and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" [21 U.S.C. § 321(m)].

In *Kordel v. United States*, 335 U.S. 345, 347, 348 (1948), where "the literature involved . . . was shipped separately from the drugs and at different times" but "had a common origin and a common destination," the literature was held to accompany the drugs in interstate commerce within the meaning of the Act [21 U.S.C. § 321(m)] and so to com-

prise [58] a part of the "labeling." [See also *United States v. Urbuteit*, 335 U.S. 355 (1948); *United States v. Research Laboratories, Inc.*, 126 F. 2d 42, 45 (9th Cir. 1942).]

As in the cases just cited, the literature involved at bar explains the claimed beneficial uses of each drug and was obviously "designed for use in the distribution and sale"; while the "label" itself is either totally or practically silent as to the purpose for which the drug is to be used; and usually, but not invariably, both the drug and the literature describing it have a common point of origin in interstate commerce. The point of difference in the case at bar is that generally speaking the article and the literature do not have a common destination, since defendants usually ship the drugs to a retail outlet, while the literature is shipped directly to prospective consumers.

Thus the precise question on this phase of the case is whether the literature may properly be held to accompany the drug in interstate commerce within the meaning of 21 U.S.C. § 321(m) (2), where the destination of the literature when shipped is not the distributor or consumer of the drug.

The policy of the Act seems clearly to require that "labeling" [21 U.S.C. § 321(m)] which bears "adequate directions for use" [21 U.S.C. § 352(f) (1)] of the drug be placed "upon the immediate container" [21 U.S.C. § 321(k), (1)], or [59] accompany the container so closely that the ordinary consumer will be apprised of all directions, cautions and other information appearing thereon.

Section 201(k) provides that “a requirement . . . that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper” [21 U.S.C. § 321(k)].

Section 201(n) provides that: “If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual” [21 U.S.C. § 321(n)]. [60]

And § 502 declares that: “A drug or device shall be deemed to be misbranded——

“(a) If its labeling is false or misleading in any particular. * * *

“(c) If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it

likely to be read and understood by the ordinary individual under customary conditions of purchase and use. * * *

“(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: * * *

“(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.” [21 U.S.C. § 352(a), (c), (f), (j).] [61]

Nothing more than a reading together of these quoted provisions of the Act is required to demonstrate the emphasis placed by the Congress upon the contents of the labeling as a means of protecting the consumer, as well as the legislative intent that the labeling so closely accompany the drug into the hands of the consumer “as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use” [21 U.S.C. § 352(c); see *Alberty Food Products v. United States*, 185 F.2d 321 (9th Cir. 1950)].

Where, as here, the literature and drugs do not have a common destination and the literature is not shipped to either a distributor or a consumer of the drug, it would be in derogation of the policy and

purposes of the Act to broaden further the content of the verb "accompany" as employed in § 201(m) (2), 21 U.S.C. § 321(m) (2). [See *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).] So it is my opinion that the scope of "accompanying" should be limited under *Kordel v. United States*, *supra*, 335 U.S. 345 and *United States v. Urbuteit*, *supra*, 335 U.S. 355, to cases where the literature has the same destination as the drug and hence will likely reach the hands of the consumer to serve the purposes for which labeling is intended. [Cf. *Alberty v. [62] United States*, 159 F. 2d 278 (9th Cir. 1947); also *Alberty Food Products v. United States*, *supra*, 185 F. 2d at 325.]

It follows that in the case at bar the literature must be held as not "accompanying" the drugs in interstate commerce and therefore as not constituting a part of the "labeling." [21 U. S. C. § 321(m) (2).] The "labels" alone then on each of the drugs in question [21 U.S.C. § 321(k)] must be held to comprise the entire "labeling" as to such drug.

There remains the question whether the "labeling" bears "adequate directions for use" within the meaning of § 502(f) (1) of the Act [21 U.S.C. § 352(f) (1)].

Labeling fails to bear "adequate directions for use," if it does not state "the purpose or condition for which the drug was intended," as well as the dosage and frequency or duration of taking prescribed, recommended or suggested in connection with the diseases or conditions of the body for which such drug is held out to the public. [See 21 U.S.C.

§§ 321(n), 352(f), 352(j), 371(a); 21 Code Fed. Regs. § 1.106 (1949); *Colegrove v. United States*, 176 F. 2d 614, 616 (9th Cir. 1949); *United States v. Various Quantities . . . "Instant Alberty Food,"* 83 F. Supp. 882, 885 (S.D. Cal. 1949).]

As Judge Bone said in *Alberty Food Products v. United States*, *supra*, 185 F.2d at 325: [63]

“We proceed upon the assumption that the ‘adequate directions for use’ mandate of Sec. 352(f) (1) requires that all who might want to use a drug . . . are at least entitled to a chance to somewhere find and examine a ‘label’ which is complete enough to . . . provide sufficient information at the time of purchase upon which intelligent determination might be made as to whether the drug is one which is prescribed, recommended, or suggested for their particular . . . ailment. We are persuaded that the law requires this much.”

The following is typical of the “labeling” of a majority of the drugs in the case at bar:

“Alberty’s
Sabinol
Homeopathic
App. 525 Pellets
Each Pellet Contains
Berberis Vulgaris
Lycopodium
Manufactured for and Packed by
Alberty Food Products
Hollywood, California

Directions:

Take 3 Pellets every 2 hours until relieved. Then 4 times daily."

Similar labels appear on defendants' products identified as:

Alberty's Vegetable Compound Capsules [Exhibit 1]; [64]

Alberty's Oxorin [Exhibit 2];

Alberty's Food Regular [Exhibit 3];

Instant Alberty Food [Exhibit 4];

Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles) [Exhibit 5];

Alberty's Sabinol [Exhibit 6];

Alberty Phloxo B Tablets [Exhibit 7];

Alberty's Phosphate Pellets [Exhibit 8];

Alberty's Ri-Co Tablets [Exhibit 10];

Alberty Special Formula Tablets [Exhibit 11];

Wheat Germ Oil [Exhibit 14];

Alberty's Lebara Pellets, Plain [Exhibit 17];

Alberty's Lebara No. 2 Pellets [Exhibit 18];

Cheno Phytolacca Berry Juice Extract Tablets and Cheno Phytolacca Berry Juice [Exhibit 20];

Cheno Combination Tablets [Exhibit 21];

Pandora Tablets [Exhibit 22];

Recal Tablets [Exhibit 23]; and

Alberty's Ca-Mo Pellets [Exhibit 27].

Such "labeling" fails to state either "the purpose or condition for which the drug was intended" or the duration of taking recommended for treatment of the diseases or conditions of the body for which

the drug is held out to the public [65] in defendants' literature.

The remaining "drugs" involved at bar, to wit:

Alberty Riol Tablets [Exhibit 9];

Alberty's Vitamin A (High Potency) Shark Liver Oil [Exhibit 12];

Alberty's Vi-C [Exhibit 13];

Alberty Vitamin B Complex Tablets with High-Potency B¹ [Exhibit 15];

Alberty's Vitamin B¹ Tablets with Supplementary Amounts of Other B-Complex Factors [Exhibit 16];

Cheno Herb Tea [Exhibit 19];

Alberty's Vio-Min Vitamin-Mineral Tablets [Exhibit 24];

Alberty R-Gon Tablets [Exhibit 25];

Alberty's Laxative Blend Tea [Exhibit 26];

Alberty's Vitamin A & G Capsules [Exhibit 28]; and

Alberty Rego [Exhibit 29].

may be classed as so-called dietary supplements and laxatives. As such "the purpose or condition for which the drug was intended" is a matter of common knowledge.

However defendants in their literature admittedly recommend these "drugs" without exception for other than commonly known uses. For example, defendants recommend their Vitamin [66] B¹ Tablets [Exhibit 16] in the pamphlet "Calcium—The Staff of Life" [Exhibit 30] for "preventing chronic ill health"; for "certain cases of heart disease" and "some cases of arthritis and neuritis"; for increas-

ing “the body’s insulin output and sugar tolerance”; and for “improving the intelligence of school children.”

Yet the only directions for use appearing on the “labeling” of Alberty’s Vitamin B¹ Tablets are: “Directions—Two Tablets, three times daily (six tablets a day) furnish $3\frac{1}{2}$ times the minimum daily requirements of Vitamin B¹ for an adult, and $1/10$ such requirements of Vitamin B².

Comment on the manifest inadequacy of such labeling to give “adequate directions for use” for the purposes recommended in defendants’ literature would be surplusage indeed.

The facts as to the “labeling” of each “drug” at bar being admitted, the Government is entitled to summary judgment for a writ of injunction permanently enjoining and restraining defendants from “the introduction or delivery for introduction into interstate commerce” [21 U.S.C. § 331(a)] of any of the “drugs” involved in this action unless and until the labeling [67] of each such “drug” bears adequate directions for the use thereof in the treatment of the diseases and conditions of the body for which defendants in their literature and other advertising prescribe, recommend or suggest its use [Colegrove v. United States, *supra*, 176 F. 2d 614; *id.*, 83 F. Supp. 880 (S.D. Cal. 1947).]

Accordingly the Government’s motion for summary judgment is granted, and the United States Attorney will submit proposed findings of fact, con-

clusions of law and judgment pursuant to local rule 7 within ten days.

June 8, 1951.

/s/ WM. C. MATHES,

United States District Judge.

[Endorsed]: Filed June 8, 1951.

[Title of District Court and Cause.]

FINDINGS OF FACT AND CONCLUSIONS OF
LAW ON APPLICATION FOR PERMA-
NENT INJUNCTION

Plaintiff having filed a Complaint and an Amended Complaint praying for a permanent injunction, and the defendants having appeared and answered, and the Court having conducted pre-trial proceedings, and the parties having filed a Pre-Trial Stipulation, and the Court having handed down a Memorandum to Counsel, and the plaintiff having filed a Motion for Summary Judgment, and the Court having considered oral argument and briefs, and handed down its Memorandum of Decision, the Court now makes the following Findings of Fact and Conclusions of Law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure:

Findings of Fact

(1) The defendant, Alberty Food Products, is a partnership having its principal place of business

at 729 N. Seward Street, Hollywood, California. The partnership also trades and does business under the name of Cheno Products. The defendants, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, are residents of the County of Los Angeles, State of California, and are primarily responsible for the policies and activities [69] of the partnership.

(2) Said defendants manufacture, pack, and distribute in interstate commerce certain products designated by name as follows: Alberty's Vegetable Compound Capsules; Alberty's Oxorin; Alberty's Food Regular; Instant Alberty Food; Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles); Alberty's Sabinol; Alberty Phloxo B Tablets; Alberty's Phosphate Pellets; Alberty Riol Tablets; Rico Tablets; Alberty Special Formula Tablets; Alberty's Vitamin A (High Potency) Shark Liver Oil; Alberty's Vi-C; Wheat Germ Oil; Alberty Vitamin B Complex Tablets with High-Potency B₁; Alberty's Vitamin B₁ with Supplementary Amounts of Other B Complex Factors; Alberty's Lebara Pellets, Plain; Alberty's Lebara Pellets, No. 2; Cheno Herb Tea; Cheno Phytolacca Berry Juice; Cheno Phytolacca Berry Juice Extract Tablets; Cheno Combination Tablets; Tablets Pandora; Recal Tablets; Alberty's Vio-Min Vitamin-Mineral Tablets; Alberty R-Gon Tablets; Alberty's Laxative Blend; Alberty's Ca-Mo Pellets; Alberty's Vitamin A and G Perles (or Capsules); Rego.

(3) Each of said products is intended for use in

the treatment, cure, mitigation, or prevention of disease in man, or is intended to affect the structure or a function of the body of man.

(4) The labels affixed to the containers of each of said drugs appear in Plaintiff's Exhibits 1-29 inclusive, which are part of the Record before the Court pursuant to the Pre-Trial Stipulation and oral stipulation at the pre-trial hearing. Said labels comprise all of the labeling of said drugs.

(5) Defendants also ship in interstate commerce collateral promotional literature relating to said drugs. Specimens of such literature appear in Plaintiff's Exhibits 30-35, which are part of the Record before the Court in the same manner as Plaintiff's Exhibits 1-29 (referred to in the preceding Finding).

(6) Defendants have used a number of different methods in their interstate distribution of promotional literature. Currently, they obtain the names and addresses of prospective customers from retail outlets to which [70] they sell the aforesaid drugs; defendants then mail said literature to such persons, and on the literature defendants print the name and address of the retail outlet that furnished such names and addresses (of prospective customers).

(7) Defendants also obtain the names and addresses of prospective customers from demonstrators who are hired by the defendants to work in retail outlets and there promote the sale of defendants'

products. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

(8) Defendants also obtain the names and addresses of prospective customers when individuals write in to the defendants for literature or to submit mail orders. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

(9) The aforesaid collateral literature, Plaintiff's Exhibits 30-35, makes therapeutic claims for said drugs in specific disease conditions and makes further claims regarding the alleged efficacy of said drugs in affecting the structures and functions of the body, as set forth in paragraph 4 of the Amended Complaint and as admitted in paragraph (5) of the Pre-Trial Stipulation.

(10) Defendants also utilize newspaper and magazine advertising in promoting the interstate sale of said drugs. In said advertising, as admitted in paragraph (10) of the Pre-Trial Stipulation, defendants make representations for said drugs which are substantially the same as the representations they make in their collateral literature (Exhibits 30-35).

(11) The labeling of each of said drugs does not bear adequate directions for use since (1) it does not

enumerate the disease conditions for which the drugs are intended and offered to the public, (2) it does not specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) it does not state the dosage and frequency and duration of administration in the treatment or prevention of each of such conditions, or for affecting such structures or functions of the body. [71]

(12) There is no genuine issue as to any material fact that remains unresolved with respect to the question whether said drugs are misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

(13) Said defendants will continue to introduce their drugs into interstate commerce with labeling that does not bear adequate directions for use unless they are restrained by this Court.

Conclusions of Law

(1) This Court has jurisdiction over the subject matter in this case and over the parties thereto, pursuant to 21 U.S.C. 332(a).

(2) Where drugs and related literature do not have a common destination, the literature does not "accompany" the drugs and hence is not "labeling" within the meaning of 21 U.S.C. 321(m). Plaintiff's Exhibits 1-29 are "labeling" within the meaning of 21 U.S.C. 321(m), but plaintiff's Exhibits 30-35 are not "labeling" within the meaning of said provision.

(3) In determining the disease conditions or other uses for which drugs are intended and offered to the public, the Court is not restricted to representations and suggestions in the “labeling” of such drugs, but should look to collateral literature, newspaper and magazine advertising, and any other medium of communication used by the manufacturer, packer, or distributor of such drugs.

(4) Under 21 U.S.C. 352(f)(1), a drug is misbranded and its labeling fails to bear “adequate directions for use” unless, among other things, the labeling (1) enumerates all of the disease conditions for which the drug is intended and offered to the public, (2) specifies the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) declares the dosage and frequency and duration of administration for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

(5) Defendants’ products are drugs within the meaning of 21 U.S.C. 321(g)(2) or (3). [72]

(6) Defendants’ drugs are misbranded within the meaning of 21 U.S.C. 352(f)(1).

(7) Plaintiff’s Motion for Summary Judgment and prayer for an injunction should be granted permanently restraining all of the defendants from introducing or causing to be introduced into interstate commerce, and from delivering or causing to be delivered for introduction into interstate commerce,

in violation of 21 U.S.C. 331(a), any of the drugs listed above in Finding Number (2) or any other drug which is misbranded within the meaning of 21 U.S.C. 352(f)(1) by reason of the failure of its labeling (1) to enumerate the disease conditions for which such drug is intended and offered to the public, (2) to specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) to state the dosage and frequency and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

(8) Plaintiff is entitled to all costs properly taxable against the defendants.

Dated this 30th day of June, 1951.

/s/ WM. C. MATHES,

United States District Judge.

The foregoing Findings of Fact and Conclusions of Law are hereby approved as to form.

Dated:

.....,

Edward J. O'Connor,

Attorney for Defendants.

Received copy of the within Findings of Fact and Conclusions of Law this 18th day of June, 1951.

/s/ EDWARD J. O'CONNOR,

Attorney for Defendants.

[Endorsed]: Filed July 2, 1951. [73]

[Title of District Court and Cause.]

ORDER GRANTING PERMANENT INJUNCTION

Plaintiff having filed a Complaint and an Amended Complaint praying for a permanent injunction, and the defendants having appeared and answered, and the Court having conducted pre-trial proceedings, and the parties having filed a Pre-Trial Stipulation, and the Court having handed down a Memorandum to Counsel, and the plaintiff having filed a Motion for Summary Judgment, and the Court having considered oral argument and briefs, and handed down its Memorandum of Decision, and the Court having filed Findings of Fact and Conclusions of Law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure,

It Is Therefore Ordered, that plaintiff's Motion for Summary Judgment and prayer for a permanent injunction be, and hereby are granted, and that the defendants, Alberty Food Products, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, and the agents, servants, employees, and attorneys of all or any one of them, and all other persons in active concert or participation with all or any of them, be and they hereby are permanently enjoined [74] and restrained from introducing or delivering for introduction into interstate commerce, and from causing the introduction or delivery for introduction into interstate commerce, directly or indirectly in any form or manner,

in violation of 21 U.S.C. 331(a), any of the following drugs,

Alberty's Vegetable Compound Capsules

Alberty's Oxorin

Alberty's Food Regular

Instant Alberty Food

Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles)

Alberty's Sabinol

Alberty Phloxo B Tablets

Alberty's Phosphate Pellets

Alberty Riol Tablets

Rico Tablets

Alberty Special Formula Tablets

Alberty's Vitamin A (High Potency) Shark Liver Oil

Alberty's Vi-C

Wheat Germ Oil

Alberty Vitamin B Complex Tablets with High-Potency B₁

Alberty's Vitamin B₁ with Supplementary Amounts of Other B Complex Factors

Alberty's Lebara Pellets, Plain

Alberty's Lebara Pellets, No. 2

Cheno Herb Tea

Cheno Phytolacca Berry Juice

Cheno Phytolacca Berry Juice Extract Tablets

Cheno Combination Tablets

Tablets Pandora

Recal Tablets

Alberty's Vio-Min Vitamin-Mineral Tablets [75]

Alberty R-Gon Tablets

Alberty's Laxative Blend

Alberty's Ca-Mo Pellets

Alberty's Vitamin A and G Perles (Or Capsules)

Rego

or any other drug which is misbranded within the meaning of 21 U.S.C. 352(f)(1), by reason of the failure of its labeling (1) to enumerate the disease conditions for which such drug is intended and offered to the public, (2) to specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) to state the dosage and frequency and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

It Is Further Ordered, that a Writ of Injunction issue accordingly.

Dated, this 30th day of June, 1951.

/s/ WM. C. MATHES,

United States District Judge.

Costs taxed at \$49.88.

The Foregoing Order Granting Permanent Injunction is hereby approved as to form.

Dated:

.....,

Edward J. O'Connor,

Attorney for Defendants.

in violation of 21 U.S.C. 331(a), any of the following drugs,

Alberty's Vegetable Compound Capsules

Alberty's Oxorin

Alberty's Food Regular

Instant Alberty Food

Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles)

Alberty's Sabinol

Alberty Phloxo B Tablets

Alberty's Phosphate Pellets

Alberty Riol Tablets

Rico Tablets

Alberty Special Formula Tablets

Alberty's Vitamin A (High Potency) Shark Liver Oil

Alberty's Vi-C

Wheat Germ Oil

Alberty Vitamin B Complex Tablets with High-Potency B₁

Alberty's Vitamin B₁ with Supplementary Amounts of Other B Complex Factors

Alberty's Lebara Pellets, Plain

Alberty's Lebara Pellets, No. 2

Cheno Herb Tea

Cheno Phytolacca Berry Juice

Cheno Phytolacca Berry Juice Extract Tablets

Cheno Combination Tablets

Tablets Pandora

Recal Tablets

Alberty's Vio-Min Vitamin-Mineral Tablets [75]

Alberty R-Gon Tablets

Alberty's Laxative Blend

Alberty's Ca-Mo Pellets

Alberty's Vitamin A and G Perles (Or Capsules)

Rego

or any other drug which is misbranded within the meaning of 21 U.S.C. 352(f)(1), by reason of the failure of its labeling (1) to enumerate the disease conditions for which such drug is intended and offered to the public, (2) to specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) to state the dosage and frequency and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

It Is Further Ordered, that a Writ of Injunction issue accordingly.

Dated, this 30th day of June, 1951.

/s/ WM. C. MATHES,

United States District Judge.

Costs taxed at \$49.88.

The Foregoing Order Granting Permanent Injunction is hereby approved as to form.

Dated:

.....,

Edward J. O'Connor,

Attorney for Defendants.

Received copy of the within Order Granting Permanent Injunction this 18th day of June, 1951.

/s/ EDWARD J. O'CONNOR,
Attorney for Defendants.

Judgment entered July 3, 1951.

[Endorsed]: Filed July 2, 1951. [76]

In the United States District Court in and for the
Southern District of California, Central Division

No. 10,322-WM Civil

UNITED STATES OF AMERICA,

Plaintiff,

vs.

ALBERTY FOOD PRODUCTS, a Partnership,
and ADA J. ALBERTY, HARRY ALBERTY,
FLORENCE ALBERTY, MARGARET
QUINN, and HELEN HACKWORTH, In-
dividually and as Co-Partners,

Defendants.

WRIT OF INJUNCTION

United States of America,
Southern District of California,
Central Division—ss.

The President of the United States of America
to Alberty Food Products, Ada J. Alberty, Harry
Alberty, Florence Alberty, Margaret Quinn, and
Helen Hackworth,

Greeting

Whereas, the United States of America has filed a Complaint and an Amended Complaint in the United States District Court for the Southern District of California, Central Division, against you, and has obtained an Order Granting Permanent Injunction, as heretofore filed and entered in the records of the Clerk of the above-named Court on July 3, 1951,

Now, Therefore, we, having regard to the matters contained in said Complaint and Amended Complaint, Do Hereby Command and Strictly Enjoin you, the said Alberty Food Products, Ada J. Alberty, Harry Alberty, Florence Alberty, [77] Margaret Quinn, and Helen Hackworth, and the agents, servants, employees, and attorneys of all or any of you, and all other persons in active concert or participation with all or any of you, from introducing or delivering for introduction into interstate commerce, and from causing the introduction or delivery for introduction into interstate commerce, directly or indirectly in any form or manner, in violation of 21 U.S.C. 331(a), any of the following drugs:

Alberty's Vegetable Compound Capsules

Alberty's Oxorin

Alberty's Food Regular

Instant Alberty Food

Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles)

Alberty's Sabinol

Alberty Phloxo B Tablets

Alberty's Phosphate Pellets
Alberty Riol Tablets
Rico Tablets
Alberty Special Formula Tablets
Alberty's Vitamin A (High Potency) Shark
Liver Oil
Alberty's Vi-C
Wheat Germ Oil
Alberty Vitamin B Complex Tablets with High-
Potency B₁
Alberty's Vitamin B₁ with Supplementary
Amounts of other B Complex Factors
Alberty's Lebara Pellets, Plain
Alberty's Lebara Pellets, No. 2
Cheno Herb Tea
Cheno Phytolacca Berry Juice
Cheno Phytolacca Berry Juice Extract Tablets
Cheno Combination Tablets
Tablets Pandora
Recal Tablets [78]
Alberty's Vio-Min Vitamin-Mineral Tablets
Alberty R-Gon Tablets
Alberty's Laxative Blend
Alberty's Ca-Mo Pellets
Alberty's Vitamin A and G Perles (or Cap-
sules)
Rego

or any other drug which is misbranded within the meaning of 21 U.S.C. 352(f)(1), by reason of the failure of its labeling (1) to enumerate the disease conditions for which such drug is intended and

offered to the public, (2) to specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) to state the dosage and frequency and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

Whereof fail not under penalty of the law thence ensuing.

Witness the Honorable William C. Mathes, Judge of the United States District Court this 11th day of July, 1951.

[Seal] EDMUND L. SMITH,
Clerk, United States District Court, Southern District of California.

By /s/ WM. R. WHITE,
Deputy.

Returns on Service of Writ attached.

[Endorsed]: Filed August 17, 1951. [79]

[Title of District Court and Cause.]

SUBSTITUTION OF ATTORNEYS

We, and each of us, hereby substitute Eugene M. Elson, Esq., as our attorney in the above-entitled matter in the place and stead of William V. O'Connor, Esq.

Dated this 29th day of June, 1951.

ALBERTY FOOD PRODUCTS,
A Partnership.

By /s/ ADA J. ALBERTY,
/s/ ADA J. ALBERTY,
/s/ HARRY ALBERTY,
/s/ FLORENCE ALBERTY,
/s/ MARGARET QUINN,
/s/ HELEN HACKWORTH,
Individually and as
Co-Partners. [86]

I hereby consent to the above Substitution.

Dated this 17th day of July, 1951.

/s/ WILLIAM V. O'CONNOR.

I hereby accept the above Substitution.

Dated this 16th day of July, 1951.

/s/ EUGENE M. ELSON.

Receipt of copy acknowledged.

[Endorsed]: Filed July 18, 1951. [87]

[Title of District Court and Cause.]

NOTICE OF APPEAL

Notice Is Hereby Given that the defendants above named, and each of them, hereby appeal to the United States Court of Appeals for the Ninth Circuit from the Order Granting Permanent Injunction and Motion for Summary Judgment entered in the above-entitled action July 3, 1951.

Dated this 24th day of July, 1951.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

Receipt of copy acknowledged.

[Endorsed]: Filed July 24, 1951. [89]

U. S. EXHIBIT No. 38
The Alberty Food Products
729 Seward
Hollywood 38, California

January 15, 1948

Oxorin Tablets

Robin Egg Blue—Sugar-Coated

Each Tablet to Weigh $9\frac{1}{4}$ Grains.

Formula:

Iron Gluconate.....	$2\frac{3}{4}$ grains
Vegetable Concentrates (AA1).....	4 grains
Spleen Substance.....	1 grain
Powdered Ginger.....	$\frac{1}{4}$ grain

[In margin]: (See Gov. Ex. 2)

Received in evidence February 20, 1950. [90]

U. S. EXHIBIT No. 39

The Alberty Food Products

729 Seward

Hollywood 38, California

Special Formula Tablets

8½-Grain Tablets—Dark Chocolate Coated

Below is formula and is correct as of date——

Feb. 5, 1946 and also verified on March 6, 1946

Each Tablet Is to Contain:

Spleen Substance.....	1	grain
Hemoglobin	1	grain
Nucleinic Acid.....	½	grain
Dicalcium Phosphate.....	3	grains
Pancreatin	¼	grain
Orchic Substance.....	½	grain
Iron Gluconate.....	0.89	grain*

(Ferrous)

Vegetable Gum Excipients q.s.

The above makes the Iron 4 times the daily requirement by taking 6 tablets per day.

Suggested Use: As a supplementary source of iron, calcium, and phosphorus, Two Tablets Before Each Meal, or Six Tablets Daily, will furnish One-Third the minimum adult requirement of Calcium; One-Fourth that of Phosphorus; and Four times that of Iron.

*Iron changed November 4, 1947.

[In margin]: (See Gov. Ex. 11).

Received in evidence February 20, 1950. [91]

U. S. EXHIBIT No. 40

The Alberty Food Products
729 Seward
Hollywood 38, California

Cheno Combination Tablets Formula

May 21, 1941

Celery & Leaves	29 lbs.
Dulse	15 lbs.
Spinach	11 lbs. 13¼ oz.
Irish Moss	11 lbs. 3¼ oz.
Psyllium Seed	7 lbs. 8 oz.
Parsley	7 lbs. 8 oz.
Iron Phosphate	1 lb. 3 oz.
DiCal. Phos.	32 lbs. 8 oz.

113 lbs. 32 oz.

or 115 lbs. total.

10-Grain Tablets

[In margin]: (See Gov. Ex. 21)

Received in evidence February 20, 1950. [92]

U. S. EXHIBIT No. 41

The Alberty Food Products

729 Seward

Hollywood 38, California

Pandora Tablets

Each Tablet to Contain:

Vitamin C	15.0	mgm.
Vitamin A	1000	I.U.
Calcium Pantothenate	5.0	mgm.
Para Aminobenzoic Acid	1.0	mgm.
Iron	7.5	mgm.
Iodine	0.15	mgm.
Sulphur	2.5	mgm.
Copper	0.25	mgm.
Manganese	4.0	mgm.
Base: Dicalcium Phosphate	0.5	grains
Yeast, Type 200	1.5	grains
Liver Extract, No. 70 A.I.	1.25	grains
Vegetable Gum Binders & Fillers, q.s.	5	grains
Tablet To Be Coated Light Chocolate, Color #15.		
Suggested Use: Two or more tablets daily.		

[In margin]: (See Gov. Ex. 22)

Received in evidence February 20, 1950. [93]

U. S. EXHIBIT No. 42

The Alberty Food Products

729 Seward

Hollywood 38, California

Recal

100 Tablets

6 Tablets Contain:

Dicalcium Phosphate1250 Mgs.

Dulse1½ Grains

Vitamin "D"App. 900 Int. Units

Binder, Dextrose, Starch, Hydrogentated Cotton

Seed Oil. Lemon Flavor.

Directions: Two Tablets 3 Times Daily, Before or
After Meals.

[In maring]: (See Gov. Ex. 23).

Received in evidence February 20, 1950. [94]

U. S. EXHIBIT No. 43

The Alberty Food Products

729 Seward

Hollywood 38, California

New R-Gon Formula

Nov. 18, 1947

Calcium Carbonate	6.75 grains
Sodium Bicarbonate	1.62 grains
Magnesium Trisilicate	2.5 grains
Bismuth Subcarbonate	0.75 grains

Sweetener

Peppermint-Flavored

(To be made up in 15½-Grain Tablets)

[In margin]: (See Gov. Ex. 25).

Received in evidence February 20, 1950.

U. S. EXHIBIT No. 44

The Alberty Food Products

729 Seward

Hollywood 38, California

Alberty Laxative Blend

30	pounds	Senna
10	"	Fennel Seed
9	"	Uva Ursi Leaves
8	"	Licorice Root
7	"	Buckthorn
6½	"	Dog Grass
5	"	Anise Seed
5	"	Nettle Leaves
3	"	Sassafras Bark
3	"	Shave Grass
2½	"	Yarrow
2½	"	Peppermint
2	"	Althae Wood
2	"	Guaiaac Wood
2½	"	Elder Flowers
1	"	Ononis Root
1	"	Buchu Leaves

100 pounds

[In margin]: (See Gov. Ex. 26)

Received in evidence February 20, 1950. [96]

[Title of District Court and Cause.]

CERTIFICATE OF CLERK

I, Edmund L. Smith, Clerk of the United States District Court for the Southern District of California, do hereby certify that the foregoing pages numbered from 1 to 99 contain the original Amended Complaint for Injunction; Order to Show Cause; Answer; Order Discharging Order to Show Cause re Preliminary Injunction; Order for Pre-Trial Proceedings; Pre-Trial Stipulation; Pre-Trial Statement of Issues as Stipulated; Memorandum to Counsel; Motion for Summary Judgment, Notice of Motion and Memorandum of Points and Authorities; Statement of Facts that are Material and Exist without Controversy; Supplemental Stipulation; Notice of Hearing of Motion for Summary Judgment; Memorandum of Decision; Findings of Fact and Conclusions of Law on Application for Permanent Injunction; Order Granting Permanent Injunction; Writ of Injunction; Substitution of Attorneys; Notice of Appeal; Statement of Points on Appeal and Separate designations of record on appeal by appellants and appellee which, together with original plaintiff's Exhibits 1 to 44, inclusive, filed pursuant to Pre-Trial Stipulation, transmitted herewith, constitute the record on appeal to the United States Court of Appeals for the Ninth Circuit.

I further certify that my fees for preparing and certifying the foregoing record amount to \$2.00 which sum has been paid to me by appellants.

Witness my hand and the seal of said District Court this 17th day of August, A.D. 1951.

[Seal] EDMUND L. SMITH,
Clerk.

By /s/ THEODORE HOCKE,
Chief Deputy.

[Endorsed]: No. 13062. United States Court of Appeals for the Ninth Circuit. Alberty Food Products, a partnership, and Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn and Helen Hackworth, Individually and as Co-partners, Appellants, vs. United States of America, Appellee. Transcript of Record. Appeal from the United States District Court for the Southern District of California, Central Division.

Filed August 18, 1951.

/s/ PAUL P. O'BRIEN,
Clerk of the United States Court of Appeals for the
Ninth Circuit.

United States Court of Appeals
for the Ninth Circuit

No. 13,062

UNITED STATES OF AMERICA,

Appellee,

vs.

ALBERTY FOOD PRODUCTS, a Partnership,
and ADA J. ALBERTY, HARRY AL-
BERTY, FLORENCE ALBERTY, MAR-
GARET QUINN and HELEN HACK-
WORTH, Individually and as Copartners,
Appellants.

APPELLANTS' DESIGNATION OF THE REC-
ORD MATERIAL TO THE CONSIDERA-
TION OF THIS APPEAL AND TO BE
PRINTED

(Note: In printing please omit caption in all documents except Amended Complaint for Injunction and Writ of Injunction and substitute the phrase "Title of District Court, Cause No. 10,322.")

The record designated as material to the consideration of this Appeal and to be printed is as follows:

1. Order to Show Cause. Filed October 7, 1949.
2. Amended Complaint for Injunction. Filed October 7, 1949.
3. Answer. Filed December 1, 1949.
4. Order discharging Order to Show Cause re preliminary injunction. Filed December 1, 1949.

5. Order for Pretrial Proceedings. Filed December 2, 1949.

6. Pretrial Statement of Issues as Stipulated. Filed February 16, 1950.

7. Pretrial Stipulation. Filed February 15, 1950.

8. Memorandum to Counsel. Filed July 13, 1950.

9. Motion for Summary Judgment and Notice of Motion. Filed July 19, 1950.

10. Statement of Facts that are material and exist without controversy. Filed July 19, 1950.

11. Supplemental Stipulation. Filed September 8, 1950.

12. Notice of Hearing of Motion for Summary Judgment. Filed February 8, 1951.

13. Memorandum of Decision. Filed June 8, 1951.

14. Findings of Fact and Conclusions of Law on Application for Permanent Injunction. Filed July 2, 1951.

15. Order Granting Permanent Injunction. Filed July 2, 1951.

16. Substitution of Attorneys. Filed July 18, 1951.

17. Writ of Injunction, dated July 11, 1951.

18. Exhibits 38 to 44, inclusive.
19. Notice of Appeal.
20. Clerk's Certificate.

Respectfully submitted,

/s/ EUGENE M. ELSON,
Attorney for Appellants.

Affidavit of Service by Mail attached.

[Endorsed]: Filed August 30, 1951.

[Title of Court of Appeals and Cause.]

STATEMENT OF POINTS ON WHICH APPELLANTS INTEND TO RELY ON THE APPEAL

Appellants hereby state the points upon which they intend to rely on Appeal:

1. The District Court erred in holding that the labeling of Appellants' drugs bearing the labels identified as Exhibits 2, 3, 4, 5, 7, 9, 11, 12, 13, 15, 16, 19, 21, 22, 23, 24, 25, 26, 28 and 29 are misbranded within the meaning of 21 U.S.C., 352 (fo(1)).

2. The District Court erred in granting Appellee's Motion for Summary Judgment as to the drugs bearing the labels identified as the exhibits referred to in paragraph 1 of this Statement.

3. The District Court erred in entering an order granting a permanent injunction and in issuing a

Writ of Injunction adjudging that the drugs bearing the labels identified by the exhibits referred to in paragraph 1 of this Statement are misbranded within the meaning of 21 U.S.C., 352 (f)(1).

4. The District Court erred in holding that a drug is necessarily and in all events misbranded, and its labeling fails to bear "adequate directions for use" under 21 U.S.C., 352 (f)(1), unless, among other things the labeling—

(1) Enumerates all of the disease conditions for which the drug is intended and offered to the public;

(2) Specifies the structures or functions of the body which it is intended to affect and for which it is offered to the public; and

(3) Declares the dosage and frequency of administration for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

5. The District Court erred in holding that the Motion for Summary Judgment and Prayer for Injunction should be granted, permanently restraining all of the Appellants from introducing, or causing to be introduced, into interstate commerce and from delivering, or causing to be delivered, for introduction into interstate commerce, any of the drugs listed in Finding No. (2) of the Findings of Fact of said District Court unless the labeling thereof—

(1) Enumerated the disease conditions for which any of said drugs were intended and offered to the public;

(2) Specified the structures or functions of the body which any of said drugs were intended to affect and for which any of said drugs were offered to the public; and

(3) Stated the dosage and frequency and duration of administration of any of such drugs for the treatment or prevention of such conditions or for affecting such structures or functions of the body.

6. The District Court erred in holding that in determining the disease conditions or other uses for which drugs are intended and offered to the public, the Court is not restricted to representations and suggestions in the "labeling" of such drugs but should look to collateral newspaper and magazine advertising and any other medium of communication used by the manufacturer, packer or distributor of such drugs.

Respectfully submitted,

/s/ EUGENE M. ELSON,

Attorney for Appellants.

Affidavit of Service by Mail attached.

[Endorsed]: Filed August 30, 1951.

[Title of Court of Appeals and Cause.]

STIPULATION

It Is Hereby Stipulated that Exhibits 1 to 35, inclusive, which are material to the consideration of this appeal, need not be printed since Appellants have agreed to file with this Court 12 sets of said Exhibits.

It Is Further Stipulated that this Stipulation shall be printed as part of the Record in this appeal.

Dated: September 6, 1951.

ERNEST A. TOLIN,
United States Attorney;

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division;

/s/ TOBIAS G. KLINGER,
Assistant U. S. Attorney,
Attorneys for Appellee.

/s/ EUGENE M. ELSON,
Attorney for Appellants.

So Ordered:

/s/ WILLIAM DENMAN,
Chief Judge;

/s/ H. T. BONE,

/s/ WM. E. ORR,
United States Circuit Judges.

[Endorsed]: Filed September 11, 1951.

